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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/010,749	12/06/2001	Jean-Louis Escary	21349/5	2921	
75	90 03/25/2003				
Mark A. Hofer			EXAMINER		
Brown, Rudnick, Freed & Gesmer One Financial Center Boston, MA 02111			GOLDBERG, JE	DLDBERG, JEANINE ANNE	
			ART UNIT	PAPER NUMBER	
			1634	1634	
			DATE MAILED: 03/25/2003		

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
	10/010,749	ESCARY, JEAN-LOUIS					
Office Action Summary	Examiner	Art Unit					
,	Jeanine A Goldberg	1634					
The MAILING DATE of this communication app							
Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status							
1)⊠ Responsive to communication(s) filed on <u>06 December 2002</u> .							
2a)☐ This action is FINAL . 2b)☑ Th	is action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims							
4) Claim(s) 1-25 is/are pending in the application.							
4a) Of the above claim(s) is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6) Claim(s) is/are rejected.							
7) Claim(s) is/are objected to.	7) Claim(s) is/are objected to.						
8) Claim(s) 1-25 are subject to restriction and/or election requirement.							
Application Papers							
9) The specification is objected to by the Examiner.							
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action. 12) The oath or declaration is objected to by the Examiner.							
'							
Priority under 35 U.S.C. §§ 119 and 120 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) All b) Some * c) None of:							
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of In	ummary (PTO-413) Paper No(s) formal Patent Application (PTO-152)					

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DETAILED ACTION

Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-14, 16, drawn to a method for determining at lest one function SNP in a gene by selecting a gene, providing a sample population, isolating the gene from the population, identifying a SNP, identifying those with functionality, classified in class 435, subclass 6.
 - II. Claims 15, drawn to a method for diagnosis of a disease by detecting aSNP, classified in class 435, subclass 6.
 - III. Claims 17, 19, drawn to a method of preparing a nucleotide sequence comprising at least one functional SNP and a polynucleotide, classified in class 536, subclass 23.1.
 - IV. Claims 18, 20 drawn to a method of preparing a polypeptide and a polypeptide, classified in class 530, subclass 350.
 - V. Claims 21, drawn to method of treating an individual having a pathology with a polynucleotide, classified in class 514, subclass 44.
 - VI. Claims 22-23, drawn to databank comprising functional SNPs, classified in class 707, subclass 3.
 - VII. Claim 24, drawn to a method of identifying SNPs using a databank, classified in class 702, subclass 27.

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VIII. Claim 25, drawn to a method of treating an individual having a pathology with a polypeptide, classified in class 514, subclass 2.

- 2. The inventions are distinct, each from the other because of the following reasons:
- A) The inventions of Groups III, IV and VI are patentably distinct products because the DNA of Group I and the protein of Group II and the databank of Group VI have different structures, properties and functions. The DNA of Group I is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The DNA can function not only for the expression of the protein but also as a probe in a nucleic acid hybridization assay and in a nucleic acid amplification assay, for example. In contrast, the polypeptide of Group II is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The polypeptide can function not only as a receptor but also for the generation of polyclonal and monoclonal antibodies and for the affinity purification of those antibodies or of ligands for the receptor. Moreover, the databank of Group VI is merely information within a computer system. While this information may be the representation of the nucleic acid or the proteins, the information is not biological material.
- B) The inventions of Group I, II, V, VII, and VIII are patentably distinct methods because they each have different objectives, different uses, different reagents and different method steps. The method of Group I is drawn to a method for determining at lest one function SNP in a gene by selecting a gene, providing a sample population,

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isolating the gene from the population, identifying a SNP, identifying those with functionality. The method of Group II is drawn to a method for diagnosis of a disease by detecting a SNP. The method of Group V is drawn to method of treating an individual having a pathology with a polynucleotide. The method of Group VII is drawn to a method of identifying SNPs using a databank. Alternatively, the method of Group VIII a method of treating an individual having a pathology with a polypeptide. Therefore the methods are distinct over one another.

- C) Inventions (III and V) and (IV and VIII) and (VI and VII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide composition comprising a functional SNP may be used in materially different ways including hybridization assays, aptamer screening methods, antisense methods, purification methods. The composition of polypeptides may be used to generate antibodies. Moreover, the databank may be used for additional storage of information. D) Group III and (VII and VIII) are patentable distinct inventions because the of Group nucleic acid is not relied upon in the method of Group VII and VIII. Instead Group VII and VIII uses polypeptides and databanks, respectively. Therefore, the inventions are novel and unobvious over one another.
- E) Group IV and (I, II, V, VII) are patentable distinct inventions because the polypeptide of Group IV is not relied upon in the method of Group I, II, V, VII. Instead

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Group I,II, V uses a polynucleotide. Group VII uses a databank. Therefore, the inventions are novel and unobvious over one another.

- F) Group VI and (I, II, V, VIII) are patentable distinct inventions because the databank of Group VI is not relied upon in the method of Group I, II, V, VII. Instead Group I, II, V uses a polynucleotide. Group VII uses a polypeptide. Therefore, the inventions are novel and unobvious over one another.
- 3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the different classifications and their divergent subject matter, restriction for examination purposes as indicated is proper.
- 4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- 5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jearline Goldberg March 11, 2003

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600